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10/523,800	11/03/2005	Peter Gibson	22409-00316-US	6209
30678	7590	09/08/2009	EXAMINER	
CONNOLLY BOVE LODGE & HUTZ LLP			BERTRAM, ERIC D	
1875 EYE STREET, N.W.				
SUITE 1100			ART UNIT	PAPER NUMBER
WASHINGTON, DC 20006			3766	
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			09/08/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/523,800	<b>Applicant(s)</b> GIBSON ET AL.
	<b>Examiner</b> Eric D. Bertram	<b>Art Unit</b> 3766

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 02 July 2009.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-4,6-14,17-23 and 26-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-4,6-14,17-23 and 26-29 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/06)  
 Paper No(s)/Mail Date 7/2/09
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_  
 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

## DETAILED ACTION

### *Response to Arguments*

1. Applicant's arguments filed 7/2/2009 have been fully considered but they are not persuasive. Applicant argues that the flange of Schugt is not "configured to fit flush against" the tissue. However, the applicant does not claim that the flange must be "configured to fit flush." Instead, the claim merely requires that the flange "is bendable by hand so that at least a portion of the at least one flange fits substantially flush against the surface of the tissue" (emphasis added). As claimed, only a portion of the flange is required to be substantially flush. As seen in figures 3 and 4, the tip of the flange will be substantially flush against the surface of the tissue when it is secured to the tissue.
2. The applicant further argues that Schugt does not describe a flange that is securable to tissue. However, since the flange is secured to the mounting plate 26, the Examiner considers the mounting plate to be a part of flange 20. Since the mounting plate is secured to tissue, the flange is inherently also secured to the tissue.
3. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "the at least one flange is configured to fit flush against and securable to the tissue [sic]") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

4. The 35 USC 102(a,e) rejections of claims 1-14 and 18-23 are still considered proper.
5. Regarding claim 17, the applicant did not address the 103(a) rejection. As such, the rejection is still considered proper.
6. Regarding the double patenting rejection in view of App. No. 10/825,359, this rejection has been withdrawn to the amendments in both applications. However, this rejection may be reapplied if future amendments again overlap in scope.

***Specification***

7. Applicant's amendments to the specification received on 7/2/2009 are acknowledged and accepted. The objection to the specification has been withdrawn.

***Priority***

8. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

***Information Disclosure Statement***

9. The information disclosure statement (IDS) submitted on 7/2/2009 was filed in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 1-4, 6-14, 18-23, 26, 28 and 29 are rejected under 35 U.S.C. 102(a,e) as being anticipated by Schugt et al. (US 6,730,015, hereinafter Schugt). Schugt discloses a medical implant, as shown in figure 3. The implant has a housing 30, from which three pliable flanges 20 and 34 extend outward therefrom (see figures 2-3). The housing is disposed on the mastoid process within the patient, and the three flanges are bendable so as to conform to, and adhere to, the tissue of the body (Col. 6, lines 23-32 and 61-67).
12. Regarding claim 2, the mastoid process is a bone, and since the flange is secured to the mounting plate 26, the Examiner considers the mounting plate to be a part of flange 20. Since the mounting plate is secured to tissue, the flange is inherently also secured to the tissue.
13. Regarding claims 3 and 4, Schugt discloses the implant to be part of a cochlear receiver/stimulator package (Col. 1, lines 25-40).
14. Regarding claim 6, the housing is inherently "positionable" within any bed or well naturally formed in the surface of the bone.
15. Regarding claims 7-10, the three flanges are shown to extend from upper and lower surfaces in opposite directions.

16. Regarding claims 11 and 12, as seen in figure 2, flange 20 can be considered extending outwardly from a location between two opposite sides of the housing. These sides are considered by the Examiner to be upper and lower surfaces.
17. Regarding claims 13 and 14, a removable plate 35 is connected to the housing with flanges 34 extending therefrom (see figure 3).
18. Regarding claim 18, flanges 34 are shown to be an integral extension of housing 30 (see figure 2).
19. Regarding claims 19-22, figure 3 shows flange 20 to be separately and removably mounted to the housing by engagement means 31, which the Examiner considers to be a "clip."
20. Regarding claim 23, since mounting plate 26 is considered by the Examiner to be a part of flange 20, the flange has orifices 28 that accommodate a tissue fixation device (Col. 6, lines 35-40).
21. Regarding claim 26, Schugt discloses the implant to comprise titanium (Col. 6, lines 22-25).
22. Regarding claims 28 and 29, tube 31 is made of silicone rubber, and coats a portion of both flange 20 and housing 30 (figure 3 and Col. 7, lines 1-10).

***Claim Rejections - 35 USC § 103***

23. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

24. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

25. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

26. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schugt in view of Legal Precedent.

27. While Schugt does not disclose the exact dimensions of the flanges, it has been held that where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device (See MPEP 2144.04 IV, *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469

U.S. 830, 225 USPQ 232 (1984)). Therefore, the dimensions recited in claim 17 are nothing more than an obvious variation to one of ordinary skill in the art.

28. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schugt in view of Berrang et al. (US 2002/0019669, hereinafter Berrang). Schugt, as described above, discloses the applicant's basic invention. Schugt additionally discloses that the flange may be permanently attached to the housing such that the flange remains implanted in the subject, and that a "detachable" connection includes a connection that needs to be cut (Col. 6, lines 45-60). Schugt is silent, however, to the connection be a weld. However, the use of welding parts together in the medical art is notoriously old and well known. As one example, attention is directed to the secondary reference of Berrang, which teaches the use of welding parts together in an implantable cochlear device (par. 0018 and 0025). This is because welding includes the known benefits of being extremely strong and resilient. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify Schugt such that the flange is welded to the housing, since such a connection has known benefits, and yet still could be detached by cutting, as required by Schugt.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric D. Bertram whose telephone number is (571)272-3446. The examiner can normally be reached on Monday-Thursday from 9-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on 571-272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric D. Bertram/  
Examiner, Art Unit 3766